



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Waleed H. Hassanein

Application No.: 09/534,092

Group Art Unit: 1651

Filed: March 23, 2000

Examiner: Sandra E. Saucier

Confirmation No.: 9125

Title: COMPOSITIONS, METHODS AND DEVICES FOR MAINTAINING
AN ORGAN

CERTIFICATE OF MAILING OR TRANSMISSION	
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Kelley A. Fass	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited references be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references AV6 and AW6 are enclosed.
- ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references AA-AK, AA2, AL-AP, AR-AZ, AR2-AA2, AR3-AZ3, AR4-AZ4, AR5-AZ5, AR6-AU6 and AX6-AY6 were entered in prior application, U.S. Application No. 08/936,062 and prior U.S. Application No. 09/054,698, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contain copies of the cited references.
- ☒ The listed references (AL, AM, AN, AO, AP, AR, AS, AT and AU) were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for reference AW6 under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Request for Continued Examination Transmittal. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

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Concord, MA 01742-9133

Dated: December 29, 2004

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2601.1001-009		APPLICATION NO. 09/534,092	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION December 29, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Waleed H. Hassanein		FILING DATE March 23, 2000	
		EXAMINER Sandra E. Saucier		CONFIRMATION NO. 9125	
				GROUP 1651	

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE/ MM-DD-YYYY	NAME OF PATENTEE OF CITED DOCUMENT
	AA	5,599,173	02/04/1997	Chen <i>et al.</i>
	AB	5,472,876	12/05/1995	Fahy
	AC	5,498,427	03/12/1996	Menasche
	AD	5,586,438	12/24/1996	Fahy
	AE	5,807,737	09/15/1998	Schill <i>et al.</i>
	AF	3,738,914	06/12/1973	Thorne <i>et al.</i>
	AG	5,494,822	02/27/1996	Sadri
	AH	5,716,378	02/10/1998	Minten
	AI	5,770,149	06/23/1998	Raible
	AJ	5,786,136	07/28/1998	Mayer
	AK	5,362,622	11/08/1994	O'Dell <i>et al.</i>
	AA2	3,995,444	12/07/1976	Clark <i>et al.</i>
	AB2			
	AC2			
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	EPO 376 763 A	07/04/1990	McKelvey <i>et al.</i>		
	AM	WO 88/05261A	07/28/1988	TOPS SYSTEMS, INC.		
	AN	WO 96/29865A	10/03/1996	ORGAN, INC.		
	AO	WO 95/31897A	11/30/1995	VEC TEC, INC.		
	AP	WO 97/46091A	12/11/1997	MEDTRONIC, INC.		
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Barinov, E.F., "Hormonal-metabolic disturbances during biological preservation of the heart," <i>Chemical Abstracts</i> , 99(9) Abstract No. 65043 (29 Aug. 1983). <i>Fiziol. ZH.</i> , 29(3):293-299 (1983).
AS	Hulsmann, W.C., <i>et al.</i> , "Loss of cardiac contractility and severe morphologic changes by acutely lowering the pH of the perfusion medium: protection by fatty acids," <i>Chemical Abstracts</i> , 112(21) Abstract No. 196098 (21 May 1990). <i>Biochem. Biophys. Acta.</i> , 1033(2):214-218 (1990).
AT	Grynberg, A., <i>et al.</i> , "Fatty acid oxidation in the heart," <i>Chemical Abstracts</i> , 125(21) Abstract No. 271077 (18 November 1996). <i>J. Cardiovasc. Pharmacol.</i> , 28 (suppl):S11-S17 (1996).
AU	Probst, I., <i>et al.</i> , "Carbohydrate and fatty acid metabolism of cultured adult cardiac myocytes", <i>Chemical Abstracts</i> , 104(25) Abstract No. 222497 (23 June 1986). <i>Am. J. Physiol.</i> , 250(5) Pt. 2:H853-H860 (1986).
AV	Chien, <i>et al.</i> , "Canine Lung Transplantation After More Than Twenty-four Hours of Normothermic Preservation," <i>The Journal of Heart and Lung Transplantation</i> , 16(3):340-351 (1997).
AW	Chien, <i>et al.</i> , "Functional Studies of the Heart During a 24-Hour Preservation Using a New Autoperfusion Preparation," <i>The Journal of Heart and Lung Transplantation</i> , 10(3):401-408 (1991).
AX	Chien, <i>et al.</i> , "A Simple Technique for Multiorgan Preservation," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 95(1):55-61 (1988).
AR	Philippe Menasché, <i>et al.</i> , "Improved Recovery of Heart Transplants With A Specific Kit of Preservation Solutions," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 105(2):353-363 (1993).
AZ	Vinten-Johansen, <i>et al.</i> , "Reduction in Surgical Ischemic-Reperfusion Injury With Adenosine and Nitric Oxide Therapy," <i>Annals of Thoracic Surgery</i> , 60:852-857 (1995).
AR2	Lasley, <i>et al.</i> , "Protective Effects of Adenosine in the Reversibly Injured Heart," <i>Annals of Thoracic Surgery</i> , 60:843-846 (1995).
AS2	Wicomb, <i>et al.</i> , "Cardiac Transplantation Following Storage of the Donor Heart by a Portable Hypothermic Perfusion System," <i>The Annals of Thoracic Surgery</i> , 37(3):243-248 (1984).
AT2	Hardesty, <i>et al.</i> , "Autoperfusion of the Heart and Lungs for Preservation During Distant Procurement," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 93(1):11-18 (1987).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AU2	Calhoon, <i>et al.</i> , "Twelve-Hour Canine Heart Preservation with a Simple, Portable Hypothermic Organ Perfusion Device," <i>Annals of Thoracic Surgery</i> , 62:91-93 (1996).
AV2	Rao, <i>et al.</i> , "Donor Blood Perfusion Improves Myocardial Recovery After Heart Transplantation," <i>The Journal of Heart and Lung Transplantation</i> , 16(6):667-673 (1997).
AW2	Burt, <i>et al.</i> , "Myocardial Function After Preservation for 24 Hours," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 92(2):238-246 (1986).
AX2	Wicomb, <i>et al.</i> , "Orthotopic Transplantation of the Baboon Heart After 20 to 24 Hours' Preservation By Continuous Hypothermic Perfusion With an Oxygenated Hyperosmolar Solution," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 83(1):133-140 (1992).
AY2	Chambers, <i>et al.</i> , "Long-Term Preservation of the Heart: The Effect of Infusion Pressure During Continuous Hypothermic Cardioplegia," <i>The Journal of Heart and Lung Transplantation</i> , 11(4), 665-675 (1992).
AZ2	Pearl, <i>et al.</i> , "Loss of Endothelium-Dependent Vasodilatation and Nitric Oxide Release After Myocardial Protection With University of Wisconsin Solution," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 107(1): 257-264 (1994)
AR3	Lefer, <i>et al.</i> , "Attenuation of Myocardial Ischemia-Reperfusion Injury With Nitric Oxide Replacement Therapy," <i>Annals of Thoracic Surgery</i> , 60:847-851 (1995).
AS3	Seccombe, <i>et al.</i> , "Coronary Artery Endothelial Function After Myocardial Ischemia and Reperfusion," <i>Annals of Thoracic Surgery</i> , 60:778-787 (1995).
AT3	Hartman, J. Craig, "The Role of Bradykinin and Nitric Oxide in the Cardioprotective Action of ACE Inhibitors," <i>Annals of Thoracic Surgery</i> , 60:789-792 (1995).
AU3	Rinder, <i>et al.</i> , "Blockade of C5a and C5b-9 Generation Inhibits Leukocyte and Platelet Activation During Extracorporeal Circulation," <i>The Journal of Clinical Investigation, Inc.</i> , 96:1564-1572 (1995).
AV3	Aoki, <i>et al.</i> , "Anti-CD18 Attenuates Deleterious Effects of Cardiopulmonary Bypass and Hypothermic Circulatory Arrest in Piglets," <i>J Card Surg.</i> , 10:407-417 (1995).
AW3	Rosenkranz, Eliot R., "Substrate Enhancement of Cardioplegic Solution: Experimental Studies and Clinical Evaluation," <i>Annals of Thoracic Surgery</i> , 60:797-800 (1995).

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2601.1001-009		APPLICATION NO. 09/534,092	
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				GROUP 1651	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AX3	Engelman, <i>et al.</i> , "Influence of Steroids On Complement and Cytokine Generation After Cardiopulmonary Bypass," <i>Annals of Thoracic Surgery</i> , 60:801-804 (1995).
AY3	Boyle, <i>et al.</i> , "Ischemia-Reperfusion Injury," <i>Annals of Thoracic Surgery</i> , 64:524-530 (1997).
AZ3	Li, <i>et al.</i> , "Functional Recovery In Rabbit Heart After Preservation With a Blood Cardioplegic Solution and Perfusion," <i>The Journal of Heart and Lung Transplantation</i> , 12(2):263-270 (1993).
AR4	Secombe, <i>et al.</i> , "Coronary Artery Endothelial Function After Myocardial Ischemia and Reperfusion," <i>Annals of Thoracic Surgery</i> , 60:778-788 (1995).
AS4	Mankad, <i>et al.</i> , "Endothelial Dysfunction Caused By University of Wisconsin Preservation Solution In The Rat Heart," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 104(6):1618-1624 (1992).
AT4	Sunamori, <i>et al.</i> , "Relative Advantages of Nondepolarizing Solution to Depolarizing University of Wisconsin Solution in Donor Heart Preservation," <i>Transplantation Proceedings</i> , 25(1):1613-1617 (1993).
AU4	Pinsky, <i>et al.</i> , "Restoration of the cAMP Second Messenger Pathway Enhances Cardiac Preservation for Transplantation in a Heterotopic Rat Model," <i>The American Society for Clinical Investigation, Inc.</i> , 92:2944-3002 (1993).
AV4	Richens, <i>et al.</i> , "Clinical Study of Crystalloid Cardioplegia vs. Aspartate-Enriched Cardioplegia Plus Warm Reperfusion For Donor Heart Preservation," <i>Transplantation Proceedings</i> , 25(1):1608-1610 (1993).
AW4	Finn, <i>et al.</i> , "Effects of Inhibition of Complement Activation Using Recombinant Soluble Complement Receptor 1 On Neutrophil CD11B/CD18 and L-Selectin Expression and Release of Interleukin-8 and Elastase in Simulated Cardiopulmonary Bypass," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 111(2):451-459 (1996).
AX4	Wicomb, <i>et al.</i> , "24-Hour Rabbit Heart Storage With UW Solution," <i>Transplantation Proceedings</i> , 48(1):6-9 (1989).
AY4	Menasché, <i>et al.</i> , "Experimental Evaluation of Celsior®, A New Heart Preservation Solution," <i>European Journal of Cardiothoracic Surgery</i> , 8:207-213 (1994).
AZ4	Ferrera, <i>et al.</i> , "Comparison of Different Techniques of Hypothermic Pig Heart Preservation," <i>Annals of Thoracic Surgery</i> , 57:1233-1239 (1994).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR5	Gundry, <i>et al.</i> , "Successful Transplantation of Hearts Harvested 30 Minutes After Death From Exsanguination," <i>Annals of Thoracic Surgery</i> , 53:772-775 (1992).
AS5	Demertzis, <i>et al.</i> , "University of Wisconsin Versus St. Thomas' Hospital Solution For Human Donor Heart Preservation," <i>Annals of Thoracic Surgery</i> , 55:1132-1137 (1993).
AT5	Segel, <i>et al.</i> , "Recovery of Sheep Hearts After Perfusion Preservation or Static Storage With Crystalloid Media," <i>The Journal of Heart and Lung Transplantation</i> , 17(2):211-221 (1998).
AU5	Schwalb, <i>et al.</i> , "New Solution For Prolonged Myocardial Preservation For Transplantation," <i>The Journal of Heart and Lung Transplantation</i> , 17(2):222-229 (1998).
AV5	The DuPont Merck Pharmaceutical Co., Product Literature For "ViaSpan® (BELZER UW) Cold Storage Solution," (1996).
AW5	Drexler, <i>et al.</i> , "Effect of L-Arginine On Coronary Endothelial Function In Cardiac Transplant Recipients," <i>Circulation</i> , 89(4):1615-1623 (1994).
AX5	Sato, <i>et al.</i> , "Supplemental L-Arginine During Cardioplegic Arrest and Reperfusion Avoids Regional Postischemic Injury," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 110(2):302-314 (1995).
AY5	Article "The Effect Of Machine Perfusions For Preservation Versus Cold Storage On The Function Of Kidneys From Non-Heart-Beating Donors," <i>Transplantation Proceedings</i> , 57(2):293-294 (1994).
AZ5	Tesi, <i>et al.</i> , "Pulsatile Kidney Perfusion For Preservation And Evaluation: Use of High-Risk Kidney Donors to Expand the Donor Pool," <i>Transplantation Proceedings</i> , 25(6):3099-3100 (1993).
AR6	Shirakura, <i>et al.</i> , "Multiorgan Procurement From Non-Heart-Beating Donors By Use of Osaka University Cocktail, Osaka Rinse Solution, and the Portable Cardiopulmonary Bypass Machine," <i>Transplantation Proceedings</i> , 25(6):3093-3094 (1993).
AS6	Matsuno, <i>et al.</i> , "Effectiveness of Machine Perfusion Preservation As A Viability Determination Method For Kidneys Procured From Non-Heart-Beating Donors," <i>Transplantation Proceedings</i> , 26(4):2421-2422 (1994).
AT6	Habazetti, <i>et al.</i> , "Improvement in Functional Recovery of the Isolated Guinea Pig Heart After Hyperkalemic Reperfusion With Adenosine," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 111(1):74-84 (1996).

EXAMINER	DATE CONSIDERED
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DATE CONSIDERED